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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,763	04/13/2006	Shigehiko Mizutani	47234500500US	3821

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DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,763	MIZUTANI, SHIGEHIKO	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/06, 2/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group III, claims 11-15, in the reply filed on February 28, 2007 is acknowledged.

2. Claims 1-10 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 28, 2007.

3. Claims 11-15 are under examination.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on April 13, 2006 and February 28, 2007 have been fully considered and an initialed copy of the IDS is included in the mailing of this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-15 are indefinite for reciting "the intensity of the specific antigen-antibody reaction" in claim 11 lines 8 and 10. It is not clear what the reaction is. Antigens and antibodies typically bind to each other unless they are catalytic antibodies and have an enzymatic reaction.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for prognostic evaluation of P-LAP positive carcinomas, does not reasonably provide enablement for prognostic evaluation of just any carcinoma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman.

> They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are broadly drawn to a method for prognostic evaluation of carcinoma by correlating the intensity of a specific antigen-antibody reaction with prognosis of carcinoma. The specification discloses a method for correlating the amount of P-LAP antigen-antibody specific binding with a prognosis for cancer survival in endometrial carcinoma and endometriod carcinoma. Applicant has not provided any direction or guidance to assist one skilled in the art in the prognosis of just any cancer survival.

Stinghen, et al. (Journal of Biomedicine and Biotechnology, 2006, pages 1-8) teach detection of P-LAP in serum of smokers, pregnant patients, and patients with ovary embryonal carcinoma. Stinghen, et al. teach P-LAP serum concentrations are elevated in smokers (page 1 bottom of 2nd column) and cannot be easily distinguished between P-LAP and P-LAP-like enzymes using polyclonal or monoclonal antibodies (page 2 middle of 1st column).

There is insufficient evidence that would lead the skilled artisan to predict the prognosis of cancer survival in just any cancer. The specification does not teach how just any cancer can be correlated to the detection of P-LAP.

In view of the lack of predictability of the art to which the invention pertains and the lack of established protocols for the detection of P-LAP in just any cancer, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's

specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for prognosis of cancer, commensurate in scope with the claimed invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Suzuki, et al. (Clinical Cancer Research, April 2003. Vol. 9, pages 1528-1534, as cited on the IDS).

The claims recite a method for prognostic evaluation of carcinoma which comprises contacting carcinoma tissues obtained from carcinoma patients with an anti-P-LAP antibody, measuring the intensity of the specific antigen-antibody reaction between P-LAP present in the carcinoma tissues and anti-P-LAP antibody and correlating the intensity of the specific antigen-antibody reaction with prognosis of carcinoma, wherein the carcinoma is endometrial endometriod adenocarcinoma, cervical carcinoma, or ovarian carcinoma, wherein the anti-P-LAP antibody is an anti-human P-LAP polyclonal antibody.

Suzuki, et al. teach enhanced P-LAP expression in high-grade adenocarcinomas (figure 1, page 1530) detected by immunohistochemistry with an anti-human polyclonal P-LAP antibody (page 1529, 1st column). Since the claims do not define the specific P-LAP antibody and since Suzuki, et al. performed steps a, b, and c of claim 11, wherein increased expression correlated with increased grade or prognosis, all the limitations of the claims have been met.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

April 6, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER